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(54) Title: AREAL IMPLANT

(57) Abstract: An areal implant has a long-term stable, mesh-like basic structure which has pores of a size in the range from 1.5 mm to 8 mm and is provided, at least in a part area, on both sides with a synthetic, resorbable polymer film. The two polymer films are glued or welded together in pores of the basic structure.

Areal Implant

The invention relates to an areal implant and a process for the manufacture of such an implant.

Often, after the intraperitoneal implantation of polymer meshes, adhesions of internal structures occur, such as intestine, omentum, etc. Possibilities have therefore been sought for years of preventing adhesion in the area of the implant, both in the centre and the periphery, or at least to reduce its intensity.

An implant marketed by Gore under the name Dualmesh®, which is not a mesh, but a PTFE membrane, has pores on one side in order to facilitate a better tissue integration. With regard to adhesions, this implant displays favourable behaviour; it is not incorporated sufficiently into the tissue, however.

The Sepramesh® implant from Genzyme is a heavyweight polypropylene mesh which contains a film consisting essentially of natural substances (carboxymethylcellulose and hyaluronic acid) but which is brittle.

Sofradim markets under the name Parietex-Composite® a polyester mesh coated with bovine collagen which has its own problems caused by BSE and proteins not occurring naturally in the body and cannot be cut to size according to the manufacturer's instructions.

US 6,162,962 mentions that implantable polymer meshes can also be strengthened with resorbable films, but discloses no method for the preparation of large-pored meshes which are connected in

a sufficiently stable manner to a thin, sensitive, resorbable polymer film. Furthermore, there is no mention of an intraperitoneal application or reference to the reduction of adhesions.

WO 93/17635 shows two-layered composite implants which consist of a porous layer, which is to promote the growing-in of tissue and also to bring about an inflammatory reaction, and a barrier, which is intended to counteract postoperative adhesions.

JP 03295561 discloses films which contain collagen, have a mesh-like structure and are intended to prevent adhesions.

R. Dinsmore et al. (J. Am. College of Surgeons 191(2), pp. 131-6 (August 2000)) describe the reduction of adhesions with the help of "Seprafilm" (Genzyme), a mixture of a natural product and a modified natural product (hyaluronic acid and carboxymethylcellulose), during the treatment of abdominal wall defects with a polypropylene mesh. "Seprafilm" has the disadvantage that it is relatively brittle when dried and has to be pre-wetted before the surgery.

WO 99/51163 shows resorbable polymer meshes which are covered with different resorbable polymer layers, the second layer being intended to resorb more slowly.

WO 90/00410 describes the reinforcing of polymer films with partly or completely resorbable polymers.

WO 00/67663 discloses a hernia-repair mesh that contains an incision and is covered at one end with a membrane which is intended to prevent the adhesion of the spermatic cord. Such a mesh cannot be used for abdominal wall defects due to the incision and cannot be cut to size everywhere.

US 5,743,917 describes non-resorbable, heavyweight polypropylene meshes customary in the trade, which are covered with a non-

resorbable layer of PTFE which is not to be incorporated into the tissue.

WO 01/43789 shows meshes layered with hyaluronic acid and carboxymethylcellulose.

It is the object of the invention to provide a well tolerated areal implant which reduces the formation of fusions (adhesions) of internal structures in human or animal organisms, but also facilitates the growing-in of the tissue naturally occurring in the body after a short time.

This object is achieved by an implant with the features of claim 1. Claim 14 relates to a process for the manufacture of such an implant. Advantageous designs of the invention result from the dependent claims.

The areal implant according to the invention has a long-term-stable, mesh-like basic structure with pores, the size of which over more than 90% of the total area of the pores lies in the range from 1.5 mm to 8 mm. The basic structure is provided, at least in a part area, on both sides with a synthetic, resorbable polymer film, the two polymer films being glued or welded together in pores of the basic structure. The pore size is the greatest width of the respective pore of the mesh-like basic structure.

As the two polymer films are glued or welded together in pores of the basic structure, the individual layers of the implant according to the invention are reliably connected to each other. Depending on the type of materials used, the polymer films can additionally also be glued or welded to the basic structure.

In contrast to the view that a porous and a smooth side are needed in order to support the growing-in of tissue on one side of the implant and to reduce the tendency to adhesions on the

other side, a polymer film is provided on both sides in the case of the implant according to the invention. The advantage of this is that a barrier is present in the first phase after implantation on both sides which minimises adhesions. After some days or weeks (e.g. when the pseudoperitoneum has formed) this barrier breaks up, however, upon resorption of the polymer films, and tissue can grow in.

A further advantage when using the implant according to the invention is that if both sides of the implant are of the same design, consideration need not be given to which side, e.g., is to face the intestine. Thus there is no danger of confusing the two sides, and cumbersome techniques such as are used with some conventional implants (manual marking of one side directly before implantation) become superfluous.

Due to the relatively large pores, the implant according to the invention is as a rule light and thus well tolerated. The entire area of the pores preferably accounts for at least 50% of the basic area of the mesh-like basic structure.

There are many possibilities for the arrangement of the two opposite-facing films or film pieces. For example, the film pieces need not be congruent. It is also conceivable that several sections are present on the mesh-like basic structure in which the basic structure is provided with a synthetic, resorbable polymer film on both sides. In a preferred version, the basic structure is provided with polymer film on both sides in its central section, while it lies exposed in an edge area. Furthermore, polymer film can project beyond the edge of the basic structure at least on one side of the basic structure and at least in one edge area of the basic structure. In one version the basic structure is completely enclosed between two layers of polymer film which extend beyond the edge of the basic structure and are there connected to each other.

The polymer films can be closed (i.e. without pores) but can also have openings, at least in a part area.

In a preferred version, at least in a part area of the basic structure, the polymer films are connected over their whole surface to the basic structure or the respective polymer film on the opposite side, but a pointwise connection is also conceivable.

The basic structure can contain, in addition to a long-term stable polymer, a resorbable polymer, the resorbable and the long-term stable polymer preferably containing monofilaments and/or multifilaments.

By a long-term-stable polymer is meant a non-resorbable polymer or a very slowly resorbable polymer which still possesses at least 50% of its original tearing strength 60 days after the implantation. The latter group also includes substances such as e.g. polyamide, which generally are regarded as resistant, as they are not designed as resorbable material, but are attacked over time by body tissue and tissue fluids. Particularly preferred materials for the basic structure are polypropylene and mixtures of polyvinylidene fluoride and copolymers of vinylidene fluoride and hexafluoropropene, but other materials are also conceivable. Both monofilaments and multifilaments come into consideration.

Particularly suitable materials for the polymer films are poly-p-dioxanone, copolymers of glycolide and lactide (e.g. in the ratio 9:1) and mixtures of poly-p-dioxanone and polyethylene glycol, but other synthetic, resorbable materials are also possible.

The basic structure is preferably weft-knitted or warp-knitted. Preferred thicknesses for the polymer films lie in the range from 10 μm to 300 μm, in particular between 10 μm and 50 μm.

In the case of an intraperitoneal application of the implant according to the invention, adhesions are very largely prevented and after a short time tissue naturally occurring in the body has grown through the implant, which is covered by a new peritoneum (pseudoperitoneum).

Surprisingly, in particular lightweight, large-pored, thin, flexible, non-resorbable polymer meshes which are bound on both sides with only a thin, resorbable, synthetic polymer film can be prepared simply, well and with sufficient stability. These implants are easily cut to size. The adhesion of internal organs is largely prevented in the central region and also in the edge area of the implant. It is particularly advantageous if the polymer film covers a peritoneal defect in the abdominal wall only in the central area of the basic structure. In addition, the implants display good handling properties in the non-resorbed state and a certain shape memory, so that they can be easily unfolded even after a trocar passage. Further advantages are the biocompatability, the minimized allergenic potential (as only synthetic polymers are used) and the low risk of infection, which can pose a problem with natural substances, such as proteins or sugars.

Along with these properties the implants according to the invention are characterized in that tissue grows surprisingly quickly and well into the implant. This is caused by the fact that, although the actual resorption of the polymers of the resorbable films can last some months, the integrity and the stability of the films is already reduced after less than 4 weeks with the preferred materials and these decompose into small fragments between which new tissue can grow in. No very quickly decomposing polymers, which would release a high local amount of metabolites (e.g. lactic acid or glycolic acid) in a short time, are necessary, but tissue integration and polymer decomposition are essentially uncoupled, so that wound-healing processes and the

development of a new peritoneum over the implant can take place largely undisturbed.

The invention is explained further in the following using embodiments. The drawing shows in

Figure 1 the structure and the thread course of the mesh-like basic structure according to Examples 4 and 5.

Example 1: Polydioxanone film on mesh on both sides

A mesh was prepared as a mesh-like basic structure of an implant from 3-mil-thick Pronova® monofilaments (1 mil = 0.0254 mm) in warp and two part-wefts on a Müller 8-feed Raschelina RD3MT3 420 SN type laboratory machine. Pronova® (Ethicon) is a mixture of polyvinylidene fluoride and a copolymer of vinylidene fluoride and hexafluoropropene. The needles of the machine were laid 1 full/1 empty and the threads worked with a stitch density of 18.6 stitches/cm. The associated pattern notation is given in Table 1.

A piece of this mesh measuring 10 cm by 10 cm was thermally fused on both sides, each with a round film (diameter 6 cm) of poly-p-dioxanone of 25 µm thickness, such as is used for the Ethicon product "Durapatch". The upper hot plate had a temperature of somewhat over 100°C, the lower hot plate one of under 70°C. After being kept for approx. 2 minutes under slight pressure and then cooled, the sample, which lay below on several layers of baking paper and was covered above with one layer, was removed from the hot press.

An implant resulted which was partially enclosed in very largely hole-free film, displayed no sharp-edged transitions between mesh and film and could be easily cut to size in the edge area without becoming sharp-edged in the process.

Example 2: Whole-surface both-side polydioxanone film on mesh

A piece of mesh-like basic structure measuring 10 cm by 10 cm prepared as in Example 1 from Pronova® monofilaments (pattern notation see Table 1) was thermally gummed on both sides over the entire surface with a square, 25-µm-thick film of poly-p-dioxanone (length and width in each case 10 cm) as is used in the product "Durapatch" (Ethicon).

An implant resulted which was completely enclosed in hole-free film.

Example 3: Whole-surface both-side polydioxanone film on mesh

A piece of mesh-like basic structure measuring 10 cm by 10 cm prepared as in Example 1 from Pronova® monofilaments (pattern notation see Table 1) was thermally gummed on both sides over the entire surface with a square, 25-µm-thick film of poly-p-dioxanone (length and width in each case 15 cm) as is used in the product "Durapatch" (Ethicon).

An implant resulted which was completely enclosed in hole-free film, the bound films overlapping the mesh area at the edges by approx. 2.5 cm.

Example 4: Pronova® mesh with both-side film

A mesh was prepared as a mesh-like basic structure of an implant from 3.5 mil-thick Pronova® monofilaments (1 mil = 0.0254 mm) in warp and two part-wefts on a Müller 8-feed Raschelina RD3MT3 420 SN type laboratory machine. The needles of the machine were laid

1 full/1 empty and the threads worked with a stitch density of 18.6 stitches/cm. The associated pattern notation is given in Table 1. Figure 1 shows the design and the course of the thread.

A piece of this mesh measuring 5 cm by 9 cm was thermally fused on both sides, each with a rectangular film measuring 3 cm by 7 cm made from poly-p-dioxanone of 25 µm thickness, such as is used for the Ethicon product "Durapatch", so that a film-free edge area of approx. 1 cm width formed. The upper hot plate had a temperature of somewhat over 100°C, the lower hot plate one of under 70°C. After being kept for approx. 2 minutes under slight pressure and then cooled, the sample, which lay below on several layers of baking paper and was covered above with one layer, was removed from the hot press.

An implant resulted which was partially enclosed in very largely hole-free film, displayed no sharp-edged transitions between mesh and film and could be easily cut to size in the edge area without becoming sharp-edged in the process.

Example 5: Polypropylene mesh with both-side film

The mesh-like basic structure of an implant was prepared as in Example 4, but with the difference that Pronova® was not used as material but a polypropylene monofilament of 3.5 mil thickness. Pattern notation, structure and the course of the thread can again be seen in Table 1 or Figure 1.

A piece of this mesh measuring 5 cm by 8 cm was thermally fused as in Example 4 on both sides, each with a round film (diameter 6 cm) of poly-p-dioxanone of 25 µm thickness. An implant resulted which was partially enclosed in very largely hole-free film, displayed no sharp-edged transitions between mesh and film and could be easily cut to size in the edge area without becoming sharp-edged in the process.

Table 1: Pattern notations for the Examples 1 to 5

Examples 1 to 3	Examples 4 and 5
Warp: closed pillar stitch	Warp: closed pillar stitch
Wefts:	Wefts:
L1: 6-2/6-2/6-4/8-4/8-4//	L1: 2-4/2-4/0-4/2-4/2-6//
L2: 2-6/2-6/2-4/0-4/0-4//	L2: 4-2/4-2/6-2/4-2/4-0//

Example 6: Mixed polydioxanone/PEG film on mesh

A mixed film of poly-p-dioxanone, such as is used in the product "Durapatch" (Ethicon), and polyethylene glycol (PEG; molecular weight 3350) with a PEG content of 20 wt-% was prepared by melting, mixing and thermal pressing. The film had a thickness of approx. 60 µm - 100 µm and appeared macroscopically homogeneous.

A part of the film was cut into pieces measuring 0.5 cm by 2 cm and the film pieces were placed on a piece of baking paper, 2 cm apart from each other. A "Vypro" mesh (Ethicon GmbH; composite mesh of polypropylene and, as resorbable part, Vicryl®, a copolymer of glycolide and lactide in the ratio 9:1) cut to 10 cm by 10 cm was placed thereon, and the intact remaining film onto this. Then, a pressure was exerted at a temperature of approx. 120°C for some minutes.

An implant resulted in which the composite mesh serving as mesh-like basic structure was securely anchored to the film pieces.

Example 7: Composite prepared from perforated film, mesh and film

The procedure was analogous to that of Example 2 with the difference that holes of 0.5 cm diameter with a hole-to-hole distance of 1 cm were punched out of one film in order to reduce the foreign material content.

The films were securely bonded to the mesh by a film-film bonding.

Example 8: Multifilament-light mesh with thin film

The resorbable portion was removed from a "Vypro" mesh (Ethicon) customary in the trade by boiling in soda solution and repeated washing. The polypropylene light mesh thus obtained was covered on one side with 0.5 cm wide and 10 cm long strips of an approx. 25-µm-thick film of poly-p-dioxanone, the film strips being approx. 1.5 cm apart from each other. A 25-µm-thick film of poly-p-dioxanone was laid on the other side of the mesh, into which round holes of 0.5 cm diameter had already been punched with a distance of 1.0 cm between the hole edges, such that the film strips came to rest on the film areas of the perforated film. This arrangement was fused under the conditions of Example 1.

Example 9: Preliminary test for adhesion tendency of lightweight meshes in the animal model (without peritoneal defect)

In order to test the induction of intraabdominal adhesions, different implant meshes were examined in the animal model without peritoneal defect, these being the three meshes summarized in Table 2 which were not provided with films.

Table 2: Three implant meshes

Mesh	Preparation	Type
"Vypro N"	Hydrolysis from "Vypro" according to Example 8	Large-pored (4.5 mm), lightweight polypropylene multifilament mesh
Marlex®	Market product (Bard)	Small-pored (0.15 mm), heavyweight polypropylene monofilament mesh
"Pronova"	Starting mesh Example 2	Large-pored (6.5 mm), lightweight monofilament mesh

Procedure: The standardized examination took place on 5 rabbits (with on average a body weight of 2700 g) per mesh type and examination time. The implantation took place with meshes cut to a size of 5 cm by 6 cm using the IPOM technique (intraperitoneal onlay mesh technique, see e.g. E. Simon et al., Acta Chirurgica Hungarica 38(2), pp. 205-7 (1999)). All manipulations on the animals were carried out under intravenous general anaesthesia. After positioning, shaving and desinfection a suprasymphyseal skin incision was made on both sides in the right and left lower abdomen. After preparation of the abdominal wall as far as the musculature, a muscle purse-string suture was applied using "Vicryl 3-0" (Ethicon) in the area of the three skin incisions. After the introduction of pneumoperitoneum, by means of a Verres cannula, to an intraabdominal pressure of 4 mm Hg, a trocar measuring 10/12 mm was introduced via the suprasymphyseal skin incision. After the introduction of a 10 mm/0° optic, two further trocars were introduced (right lower abdomen 5 mm trocar, left lower abdomen 10/12 mm trocar) with visibility. By drawing tight the purse-string suture with two equidirectional knots, an optimum sealing of the pneumoperitoneum was achieved and the trocar fixing with the residual thread was made possible. The placing of the meshes took place in the central upper abdomen,

in order to guarantee a direct contact with the intestine. The mesh fixing took place at all four corners and in the middle of the long side using an endoscopic multi-stapler (Endopath®, Ethicon). After the relief of the pneumoperitoneum the fascia-muscular trocar wound was closed by drawing tight the previously applied purse-string suture. Skin closure was carried out with resorbable single-button "Vicryl® 3-0" sutures. Wound covering was carried out using Nobecutan® spray.

Adhesion determination: For the qualitative-clinical appraisal and estimation of adhesion formation, a control laparoscopy was carried out in a final anaesthesia. This involved the same technique as described above with appropriate documentation by means of a video unit. For the quantitative appraisal of the adhesions, following the opening of the abdominal cavity away from the mesh and the exposing of the area of the surgery, the outlines of the adhesions between abdominal wall and mesh and also of interenteric adhesions were drawn on a clear film. With the help of computer-aided planimetry, it was possible to calculate the precise adhesion area in this way.

Result: After 7, 21 and 90 days the adhesion areas given in Table 3 were determined.

Table 3: Adhesion areas of the three implant meshes in the rabbit model

Mesh	7 days (mm^2)	21 days (mm^2)	90 days (mm^2)
"Vypro N"	155	34	122
Marlex®	1002	952	744
"Pronova"	0	80	38

This result shows the general advantage of light meshes as regards reduced adhesion formation and serves as preliminary test

for a defect model in which the adhesion-reducing effect of the implant according to the invention is demonstrated.

Example 10: Results in the abdominal wall defect model

Internal structures, such as the abdominal viscera, are usually covered by a cell layer, the peritoneum, which prevents adhesions. If the peritoneum is damaged, the implant must not only not produce adhesions, but must also reduce adhesions. Therefore in this model both abdominal wall peritoneum (parietal peritoneum) and intestine peritoneum (visceral peritoneum) were damaged.

Implantation: This model was carried out in the open technique on 5 rabbits per each implant type. The rabbits were prepared and anaesthetized for the surgery. The abdomen was shaved between costal arch and pelvic inlet. The rabbits were placed on the operating table in the dorsal position and, after positioning on a vacuum cushion, fixed at the extremities. The OP field that had been shaved was desinfected. Each rabbit was covered with sterile cover film and a small window was cut out in the implantation area. After a median skin incision to a length of approx. 8 cm between xiphoid and symphysis, the abdominal fascia was prepared on both sides of the skin incision to a total width of approx. 4 cm. After opening of the abdomen by median laparotomy to a length of approx. 6 cm an internal abdominal wall defect measuring approx. 20 mm by 60 mm was created by excision of a 1 cm-wide strip of peritoneum from both wound edges; part of the fascia transversalis was also removed. The peritoneum of the caecum was damaged with a swab by rubbing.

The meshes cut to a size of 40 mm by 80 mm, previously sterilized by ethylene oxide, were sewn into the defect onto the peritoneum in direct contact with the abdominal organs with "Prolene" suture material (Ethicon; polypropylene), thickness 3-0 (me-

tric 2), by transmural sutures using the IPOM technique (intraperitoneal onlay mesh). The laparotomy wound was continually closed with "PDS" suture material (Ethicon; poly-p-dioxanone), thickness 3-0 (metric 2). Above this, the skin was closed in interrupted suture with "Monocryl" (Ethicon; monofilament of a copolymer of glycolide and lactide), thickness 3-0 (metric 2).

After 28 days the animals were killed and the area and thickness of the adhesions were appraised. The result is summarized in Table 4.

Table 4: Experimental results of the adhesion of uncoated light meshes and light meshes provided with film in the peritoneal defect model (28 days)

Mesh	Preparation	Type	Adhesion area [%]
"Pronova"	See Table 1	Monofilament light mesh	48 ± 28
"Pronova", partly coated with PDS (poly-p-dioxanone)	Mesh measuring 4 cm by 8 cm coated on both sides with PDS film measuring 3 cm by 7 cm, analogous to Example 4	Monofilament light mesh covered on both sides with 25-µm film	7 ± 4
"Pronova", completely coated with PDS (poly-p-dioxanone)	Mesh measuring 4 cm by 8 cm coated on both sides with PDS film measuring 4 cm by 8 cm, original mesh prepared analogous to Example 4, but whole surface coated	Monofilament light mesh covered on both sides with 25-µm film	9 ± 7 (only four rabbits here)

Results: The light meshes coated with thin film (implants according to the invention) show a reduction in adhesion of over 80%, compared with the uncoated mesh, which in the preliminary tests in Example 9 (Table 3) displayed results already better by orders of magnitude than a heavy mesh customary in the trade (Marlex®). The degree of adhesion was lower with the implants according to the invention, so that the fusions could be more easily detached. In addition, a good growing-in of tissue was already seen after four weeks with these implants.

Claims

1. Areal implant with a long-term-stable, mesh-like basic structure which has pores, the size of which over more than 90% of the total area of the pores is in the range from 1.5 mm to 8 mm, and which is provided, at least in a part area, on both sides with a respective synthetic, resorbable polymer film, the two polymer films being glued or welded together in pores of the basic structure.

2. Implant according to claim 1, characterized in that the entire area of the pores accounts for at least 50% of the area of the mesh-like basic structure.

3. Implant according to claim 1 or 2, characterized in that the basic structure is provided in its central region on both sides with polymer film while lying exposed in an edge area.

4. Implant according to one of claims 1 to 3, characterized in that polymer film projects beyond the edge of the basic structure at least on one side of the basic structure and at least in one edge area of the basic structure.

5. Implant according to one of claims 1 to 4, characterized in that the polymer films are closed.

6. Implant according to one of claims 1 to 4, characterized in that the polymer films have openings at least in a part area.

7. Implant according to one of claims 1 to 6, characterized in that, at least in a part area of the basic structure, the polymer films are connected over the whole surface to the basic structure or the respective polymer film on the opposite side.

8. Implant according to one of claims 1 to 7, characterized in that, at least in a part area of the basic structure, the polymer films are connected pointwise to the basic structure or the respective polymer film on the opposite side.

9. Implant according to one of claims 1 to 8, characterized in that the basic structure contains a resorbable polymer in addition to a long-term-stable polymer, the resorbable and the long-term-stable polymer preferably containing monofilaments and/or multifilaments.

10. Implant according to one of claims 1 to 9, characterized in that the basic structure contains at least one of the materials selected from the following group: polypropylene, mixtures of polyvinylidene fluoride and copolymers of vinylidene fluoride and hexafluoropropene.

11. Implant according to one of claims 1 to 10, characterized in that the polymer films contain at least one of the materials selected from the following group: poly-p-dioxanone, copolymers of glycolide and lactide, mixtures of poly-p-dioxanone and polyethylene glycol, mixtures with polyethylene glycol, copolymers of the aforementioned substances.

12. Implant according to one of claims 1 to 11, characterized in that the basic structure is weft-knitted or warp-knitted.

13. Implant according to one of claims 1 to 12, characterized in that the polymer films have a thickness in the range from 10 µm to 300 µm, preferably less than 50 µm.

14. Process for the manufacture of an implant according to one of claims 1 to 13, wherein a long-term-stable, mesh-like basic structure, which has pores of a size in the range

from 1.5 mm to 8 mm, is covered at least in a part area on both sides with a synthetic, resorbable polymer film, and wherein the two polymer films are glued or welded together in pores of the basic structure.

15. Process for the intraperitoneal placing of an implant according to one of claims 1 to 13, the implant being introduced laparoscopically via a trocar into the human or animal organism and fixed on the peritoneum.

16. Process for the intraperitoneal placing of an implant according to one of claims 1 to 13, the implant being placed in an open technique and fixed via an incision of the abdominal wall peritoneum with the structures lying above same on the abdominal wall, optionally after previously existing fusions are detached, and the individual layers then being closed.

17. Process for the placing of an implant according to one of claims 1 to 13, the implant being placed in open technique under the rectal muscle onto the posterior portion of the rectal sheath (sublay technique), even if the peritoneum cannot be closed.

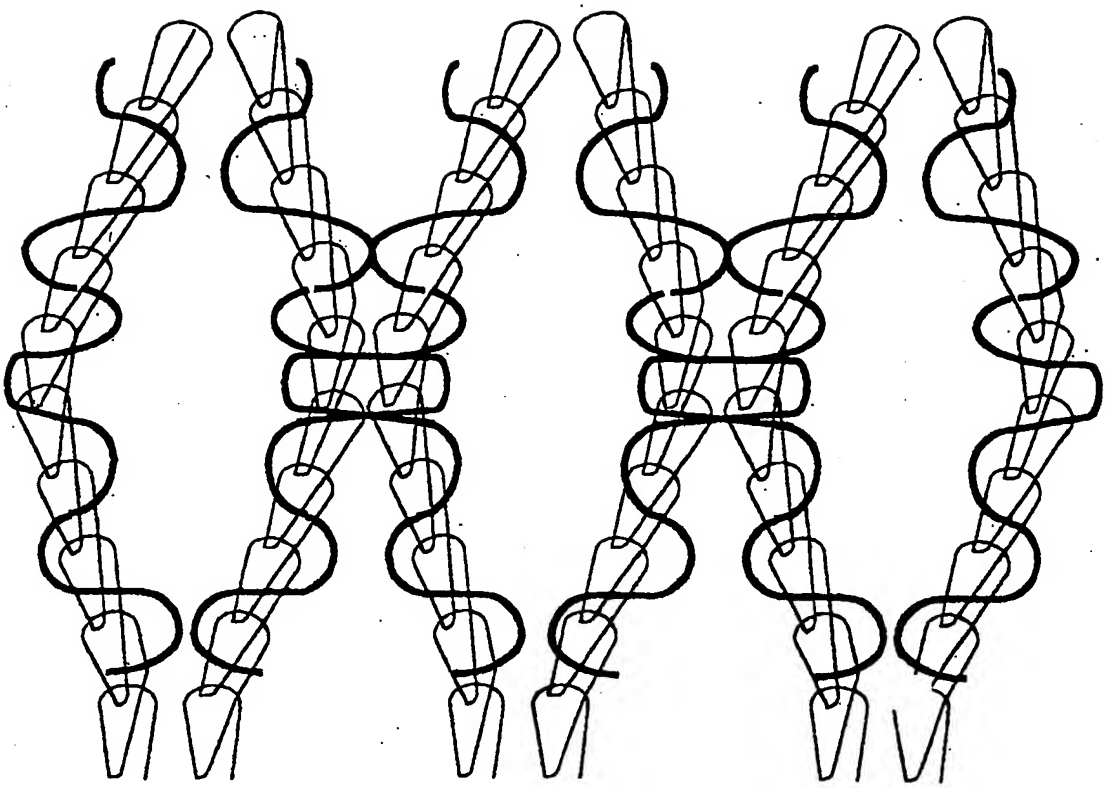

Fig. 1

NTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 02/12652

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 264 702 B1 (ORY FRANCOIS R EACUTE GIS ET AL) 24 July 2001 (2001-07-24) column 2, line 48 -column 3, line 24 column 4, line 1-38	1-17
Y	WO 01 15625 A (SCHULDT HEMPE BARBARA ;WALTHER CHRISTOPH (DE); ETHICON GMBH (DE)) 8 March 2001 (2001-03-08) page 3, line 20 -page 4, line 8	1-17
Y	EP 1 099 421 A (INST DEUTSCHE) 16 May 2001 (2001-05-16) column 2, paragraph 13 column 4, paragraph 19	1-17
A	US 5 686 090 A (DAHLKE HERMANN ET AL) 11 November 1997 (1997-11-11) the whole document	1-17

☐ Further documents are listed in the continuation of box C.

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NTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP 02/12652

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6264702 B1	24-07-2001	FR 2766716 A1	05-02-1999
		AT 204489 T	15-09-2001
		AU 8866898 A	22-02-1999
		DE 69801442 D1	27-09-2001
		DE 69801442 T2	06-12-2001
		EP 0998313 A1	10-05-2000
		ES 2163883 T3	01-02-2002
		WO 9906079 A1	11-02-1999
WO 0115625 A	08-03-2001	DE 19942611 C1	05-07-2001
		WO 0115625 A1	08-03-2001
		EP 1210031 A1	05-06-2002
EP 1099421 A	16-05-2001	DE 19954166 A1	17-05-2001
		EP 1099421 A1	16-05-2001
		EP 1099422 A1	16-05-2001
		JP 2001137330 A	22-05-2001
		JP 2001161725 A	19-06-2001
US 5686090 A	11-11-1997	AU 666600 B2	15-02-1996
		AU 5477194 A	04-08-1994
		BR 9400359 A	16-08-1994
		CA 2114282 A1	29-07-1994
		GR 1002613 B	20-02-1997
		JP 7047090 A	21-02-1995